

Office Action Summary

Application No.

09/543,188

Applicant(s)

HAMMOND ET AL.

Examiner

Zachariah Lucas

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 November 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,5,7-14 and 16-29 is/are pending in the application.
- 4a) Of the above claim(s) 17(in part) is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2, 5, 7-14, and 16-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 April 2000 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Status of the Claims

1. Claims 1, 2, 5, 7-14, and 16-29 are pending and under consideration in the present application.
2. Claims 1-75 were pending in the application prior to entry of the amendment filed November 14, 2002 (Amend. D). Amend. D cancelled claims 3, 4, 6, 15, 30-75 (claims drawn to non-elected inventions). Amendment D also amended claims 1, 9, 16, and 17.
3. Claims 1, 2, 5, 7-15, and 17-29 were rejected in the action mailed on August 14, 2002 (the prior action). The subject matter of claim 16 was indicated to be allowable.

Election/Restrictions

4. In view of the cancellation of linking claim 1, claim 17 is now directed, in part, to an invention that is independent or distinct from the invention originally claimed for the following reasons: The claim describes peptide sequences unrelated to the originally elected sequence. However, in view of the fact that each of SEQ ID NOs: 3, 4, 13, 21, 27, and originally elected claim 23 are linked by amended claim 1, and have already been searched, the restriction will not be applied between these peptides. However, there is no linkage between these sequences and the remaining sequences of SEQ ID NO: 5-12, 15-20, 22, 24-26, and 28-30.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution

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on the merits. Accordingly, the above-identified embodiments of claim 17 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

It is further noted that without such cancellation, claim 17 is not properly dependant on claim 1 (through claim 7) because the claim "limits" the invention to peptides not covered by the formula of claim 1.

Drawings

5. New corrected drawings are required in this application for the reasons indicated on the attached form PTO 948. Applicant is advised to employ the services of a competent patent draftsman outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

Claim Rejections - 35 USC § 101

6. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

7. **(Prior Rejection-Maintained)** Claim 9 was rejected under 35 U.S.C. 101, and under 35 U.S.C. 112 ¶1, because the claimed invention is not supported by either a specific or substantial asserted utility or a well-established utility. This rejection was based on an assumption that the claim is intended to read on a peptide comprising SEQ ID NO: 34, the retro-inverso isomer of

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SEQ ID NO: 1. As the claim has been amended to explicitly recite the rejected language, the applicant has not overcome the rejection.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. **(Prior Rejection- Maintained)** Claims 1, 2, 5, 7-15 and 18-29 were rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for some specific peptide ligands, does not reasonably provide enablement for any peptide ligand to a polypeptide comprising SEQ ID NO: 1 (polypeptide). The rejection is maintained for claims 1, 2, 5, 7, 8, 10-14, and 18-29. Claim 1 has been amended to read on only the peptides within the formula originally presented in claim 15, now cancelled. As stated in the prior rejection, the applicant is also not enabled for all of the peptide ligands of this claim. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

The applicant traverses this rejection on the grounds that inoperative embodiments are excluded by the claim limitations requiring that the peptides be able to bind to the identified polypeptide. However, the examiner does not agree that the presence of this functional language is satisfactory overcome the enablement rejection. As described before, the applicant has not shown a connection between peptides of the claimed formula and the ability to bind prions. Although the applicant has provided methods of screening such peptides, there is no reasonable

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expectation that those in the art would be able to find other peptides than the six disclosed that are able to bind to prions.

Further, although the claims indicate that the peptides are intended to bind any polypeptide that comprises either SEQ ID NO: 1, they do not require that the peptide be able to bind SEQ ID NO: 1. Thus, before one would know if a given peptide falls within the claims, they would have to assay the peptide against any potential polypeptide. Although there are a limited number of peptides, and running assays to determine what peptides bind any given prion polypeptide are relatively easy, in order to practice the claims many different assays would have to be performed. Even assuming that the claim was limited to ligands to full length prion proteins, one in the art would have to assay each peptide against every prion protein before they would know whether or not the claimed peptide was an operative embodiment of the claim.

In order to overcome this problem, the applicant would have to show either that all peptides according to the formula of claim 1 are capable of binding a shared sequence of prions generally (e.g. SEQ ID NO: 1), or some connection between the claimed formula and the peptides binding capability. As noted above and in the prior action, the applicant has done neither. Thus, while 360 peptides may not be an excessively large number in the relevant art, given the numerous assays would have to be conducted in order for one in the art to determine if any one given peptide falls within the claims, the lack of predictability noted in the prior action, and the lack of guidance provided by the applicant indicating which peptides are likely to fall within the claims, the examiner does not find that the applicant has enabled those in the art to practice the claimed invention without undue experimentation.

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10. **(New Rejection- necessitated by Amendment)** Claims 1, 2, 5, 7, 9, 10-14, and 16-29 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the peptides according to the six disclosed peptides that fall within the claimed formula that bind to prions, does not reasonably provide enablement for peptides according to the given formula that bind to proteins comprising retro-inverso isomers of SEQ ID NO: 1. The applicant has not shown that the peptides are capable of binding to the retro-inverso isomers. No evidence or other support has been provided to show that a peptide capable of binding to a given prion sequence would also be able to bind to the retro-inverso isomer of that sequence. The same applies equally, whether it is assumed that the peptides bind to the sequence of SEQ ID NO: 1, or to other parts of the prion polypeptide comprising that sequence.

11. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

12. **(Prior Rejection –Withdrawn)** Claim 17 was rejected in the prior action under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In view of the amendment to the claim, the rejection is withdrawn.

Claim Rejections - 35 USC § 102

13. **(Prior Rejection- Withdrawn)** Claims 1, 2, 5, 7, 8,10, 18, 20, and 29 were rejected in the prior action under 35 U.S.C. 102(b) as being anticipated by WO document 96/39834, naming

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Soto-Jara et al. as inventors (Soto-Jara). The claims read on peptides of less than 20 amino acid residues that bind to proteins comprising of either SEQ ID NO: 1 or retro-inverso isomers thereof, and to compositions comprising the peptides. As the claims have been amended to limit the claims to peptides not disclosed in this reference, the rejection is withdrawn.

14. **(Prior Rejection – Withdrawn)** Claims 1,2, 5, 7, 8, 10, 18, 20, and 29 were rejected in the prior action under 35 U.S.C. 102(e) as being anticipated by U.S. Patent Number 6,211,149, issued to Chesebro et al. (Chesebro). As the claims have been amended to limit the claims to peptides not disclosed in this reference, the rejection is withdrawn.

15. **(Prior Rejection – Withdrawn)** Claims 1, 2, 5, 7, 8, and 18 were rejected in the prior action under 35 U.S.C. 102(e) as being anticipated by U.S. Patent Number 5,750,361, issued to Stanley B. Pruisner. As the claims have been amended to limit the claims to peptides not disclosed in this reference, the rejection is withdrawn.

Claim Rejections - 35 USC § 103

16. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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17. **(Prior Rejection – Withdrawn)** Claims 11, and 20-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chesebro, in view of U.S. Patent Number 6,221,614, issued to Prusiner et al. (the 614 patent). As the claims have been amended to limit the claims to peptides not disclosed in this reference, the rejection is withdrawn.


Conclusion


18. The subject matter of claim 16 is found allowable except as it reads on ligands to retro-inverso isomers. The subject matter of claims other than claims 9 and 17 would likewise be allowable if limited to peptides or peptide compositions of the sequences in claim 16.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 703-308-4240. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4027. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.


Z. Lucas
Patent Examiner
January 22, 2003


JAMES HOUSEL 1/27/03
SUPERVISORY PATENT EXAMINER
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